Mercodia

Mall-0064 v 7.0

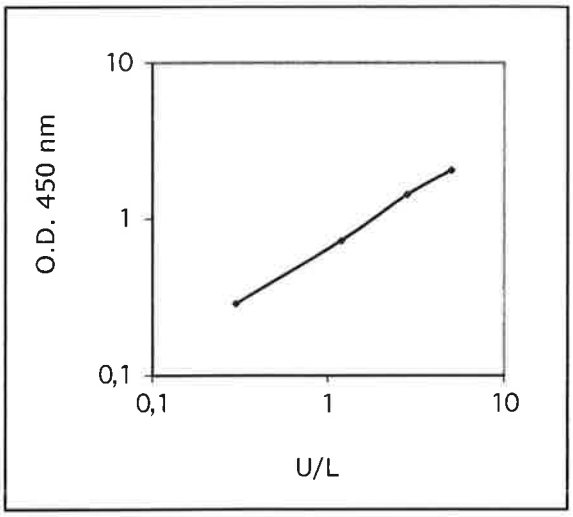
Certificate of Analysis

1. **Manufacturer**

Mercodia AB, Sylveniusgatan 8A, 754 50 Uppsala, SWEDEN

2. **Description**

Catalog no: 10-1106-01
Product: Mercodia Lp(a) ELISA
Lot no: 34008
Expiry date: 2024-03-31



Component	*Art no*	*Lot no*	*O.D. 450 nm*	*Exp. date*
Calibrator 0	20-2513	32336	0,128	2024-04-12
Calibrator 0,300 U/L	20-2514	32326	0,288	2024-05-06
Calibrator 1,19 U/L	20-2515	32327	0,726	2024-05-06
Calibrator 2,81 U/L	20-2516	32328	1,434	2024-05-06
Calibrator 5,03 U/L	20-2517	32329	2,053	2024-05-06
Coated Plate	20-2519	32331		2024-04-12
Enzyme Conjugate 11X	20-2533	32342		2024-04-20
Enzyme Conjugate Buffer	20-2524	32334		2024-04-27
Pretreatment Solution	20-2124	32340		2024-04-16
Sample Buffer 5X	20-2530	32338		2024-04-26
Wash Buffer 21X	20-6746	33635		2029-05-20
Substrate TMB	20-2629	31053		2024-07-31
Stop Solution	20-2693	32372		2028-04-22

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3. Quality control

Quality control has been performed for lot no 34008 according to standard operating procedures at Mercodia AB, and the product is released based on fulfillment of established acceptance criteria.

4. Calibration

The Mercodia Lp(a) ELISA is calibrated against a highly purified, fully validated, commercial Lp(a) preparation.

5. Assay method

Test procedure used is according to current Direction for Use for the product and lot.

6. Intended use

Mercodia Lp(a) ELISA provides a method for the quantitative determination of human Lp(a) in serum or plasma.

7. Storage and handling

Recommended storage of kit is 2-8°C.
Storage of unused or diluted kit components is stated in the Direction for Use.

8. Hazardous information

Please refer to the Material Safety Data Sheet for hazard identification.

9. Quality standard documentation

The Mercodia Quality System fulfills the QSR and the requirements for the European CE mark, the Directive 98/79/CE on *in vitro* diagnostic medical devices. Mercodia is ISO 13485 certified, for compliance with the International Quality Management System for medical devices.

10. Names and signatures of certifying officers

Date of analysis:	Performed by:	Signature:
2021-06-18	Mohammed El-Ghezzaoui /gm.	

Date of approval:	Approved by:	Signature:
2022-08-22	Elin Wernbom	EW

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